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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/080,797	02/21/2002	Romulus Kimbro Brazzell	OP/4-31881A	9942

1095 7590 09/06/2002

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EXAMINER

BERTOGLIO, VALERIE E

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 09/06/2002

6

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/080,797

Applicant(s)

BRAZZELL ET AL.

Examiner

Valerie E. Bertoglio

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-42 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-4, 16, 28, 29, drawn to a method of treating ocular neovascularization by increasing levels of endostatin in ocular tissue using endostatin protein, classified in class 514, subclass 2.
- II. Claims 1-3, 5-8, 17-22, 27-41, drawn to a method of treating ocular neovascularization by administering a viral vector comprising an endostatin-encoding nucleic acid, classified in class 514, subclass 44.
- III. Claims 1-3, 5, 9-13, 15, 23-26, 28, 29, drawn to a method of treating ocular neovascularization by administering a microcapsule comprising cells that secrete endostatin, classified in class 424, subclass 93.21.
- IV. Claims 1-3, 5, 9, 14, 28, 29, drawn to a method of treating ocular neovascularization by administering a microcapsule comprising cells that have been transfected and secrete an exogenous endostatin, classified in class 424, subclass 93.3.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are patentably distinct because, while both inventions share the same purpose, the protocols and reagents required for the methods are materially distinct and separate. Invention I requires administering endostatin protein through any means, which could include administering the protein directly, while Invention II requires administering a viral vector not required by Invention I. The methods of Inventions I and II are practiced with materially different process steps, material reagents, and technical considerations.

Inventions I and III or IV are patentably distinct because, while both inventions share the same purpose, the protocols and reagents required for the methods are materially distinct and separate. Invention I requires administering endostatin protein through any means, which could include administering the protein directly, while Inventions III or IV requires administering cells that are not required by Invention I. The methods of Inventions I and III or IV are practiced with materially different process steps, material reagents, and technical considerations.

Inventions II and III are patentably distinct because, while both inventions share the same purpose, the protocols and reagents required for the methods are materially distinct and separate. Invention II requires administering a viral vector not required by Invention III and Invention III requires cells not required by invention II. The methods of Inventions II and III are practiced with materially different process steps, material reagents, and technical considerations.

Inventions II and IV are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the method of treating ocular neovascularization can be done using cells without a vector and does not require the combination of cells transfected with a vector. The subcombination has separate utility such as a means of transfecting cells and producing endostatin *in vitro*.

Inventions III and IV are related as combination and subcombination. In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed

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because the method of treating ocular neovascularization can be done using a viral vector without cells and does not require the combination of cells transfected with a vector. The subcombination has separate utility such as a means of producing endostatin *in vitro*.

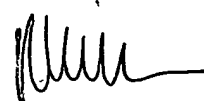
Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and their recognized divergent subject matter and because the searches for the groups are not coextensive, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Valarie Bertoglio whose telephone number is 703-305-5469. The examiner can normally be reached on 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds can be reached on 703-305-4051. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.


Valarie Bertoglio
Patent Examiner


MICHAEL C. WILSON
PATENT EXAMINER